STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

GUIDELINES FOR USE

1. Is the patient **ONE** of the following?
   - Age of at least 18 years old with a diagnosis of chronic hepatitis C, genotype 1 or 3
   - Age of 3 to 17 years old with a diagnosis of chronic hepatitis C, genotype 2 or 3

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following?
   - The patient has severe renal impairment (estimated glomerular filtration rate (GFR) less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient is currently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
   - The patient is using Sovaldi with a direct acting antiviral (e.g., Olysio or Daklinza) **AND** is concurrently taking amiodarone

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Patient has evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the last 6 months

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient under age 18?

   If yes, continue to #17.
   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following?
   - Treatment naïve **OR** treatment experienced (prior treatment with peginterferon/ribavirin)
   - Patient is without cirrhosis **OR** has decompensated cirrhosis **OR** is post-liver transplant (with or without cirrhosis)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agents? (see criteria below)
   - For genotype 1 HCV infection: a short trial of Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy to Mavyret, Harvoni or Epclusa) or contraindication to all three agents
   - For genotype 3 HCV infection: a short trial of Epclusa or Mavyret (e.g., adverse effect early in therapy to Epclusa or Mavyret) or contraindication to both agents
     (**NOTE:** An individual who has completed a full course of therapy with the preferred agent that did not achieve SVR will not be approved)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have decompensated cirrhosis?

   If yes, continue to #12.
   If no, continue to #8.

8. Is the requested medication being used with 1) ribavirin **OR** 2) peginterferon alfa and ribavirin?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #9.

9. Is this request for Sovaldi use in combination with Daklinza?
   CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

   If yes, continue to #13.
   If no, continue to #10.

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GUIDELINES FOR USE (CONTINUED)

10. Is the request for a combination regimen with Sovaldi plus Olysio in a patient with genotype 1 hepatitis C infection?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient meet **ONE** or more of the following?
    - The patient has cirrhosis
    - Patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, Incivek (telaprevir), Olysio (simeprevir), or Victrelis (boceprevir)] and has not achieved a sustained virologic response (SVR) **OR** 2) a regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
    - Patient is concurrently using any of the following medications with Sovaldi/Olysio which are not recommended by the manufacturer of Olysio:
      - Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
      - Any of the following HIV medications: delavirdine, etravirine, nevirapine, or efavirenz
      - A cobicistat-containing medication (e.g., Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz, Prezcobix, or Tybost)
      - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**

    (NOTE: Regimen approved for genotype 1 patient without cirrhosis: Olysio and Sovaldi for 12 weeks)
    CLINICAL SPECIALISTS: Patient is on combination therapy with Olysio; please also view Olysio prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Olysio.
    APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Olysio and Sovaldi.

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GUIDELINES FOR USE (CONTINUED)

12. Is this request for Sovaldi use in combination with Daklinza?
    CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Is the patient concurrently using Sovaldi/Daklinza with any of the following (contraindicated or not recommended by the manufacturer, except specified HIV medications) medications: amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine?

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.
    If no, continue to #14.

14. Does the patient have compensated cirrhosis?

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.
    If no, continue to #15.

15. Does the patient have decompensated cirrhosis or is post-liver transplant?

    If yes, continue to #16.
    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza)**
    - **Sovaldi 400mg tablets: #1 per day**
    - **Sovaldi 200mg pellets: #2 packets per day**

    CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.
    APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

16. Is the patient using a regimen of Daklinza and Sovaldi (sofosbuvir) **WITH** ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza and ribavirin)**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**

    CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.
    APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi with ribavirin.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Does the patient have genotype 2 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #18.
    If no, continue to #19.

18. Is the requested medication being used with ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**
    - **Sovaldi 150mg pellets: #1 packet per day.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have genotype 3 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #20.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

20. Is the requested medication being used with ribavirin?

If yes, **approve for 24 weeks for the requested strength by GPID or GPI-14 as follows:**

- **Sovaldi 400mg tablets: #1 per day.**
- **Sovaldi 200mg tablets: #1 per day.**
- **Sovaldi 200mg pellets: #2 packets per day.**
- **Sovaldi 150mg pellets: #1 packet per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3, **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    3. You had a short trial of the preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agents as specified below. An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved.
        i. If you have genotype 1 infection, you had a short trial of Epclusa, Harvoni or Mavyret or you have a contraindication to all three agents.
        ii. If you have genotype 3 infection, you had a short trial of Epclusa or Mavyret or you have a contraindication to both agents.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

F. **If you are a pediatric patient (under age 18) approval also requires:**
   1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
   2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

The medication will not be approved for the following:

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)
D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

For requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:

A. You are 18 years of age or older
B. You do not have cirrhosis (liver scarring)
C. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir) **OR** 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

D. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use the drug) or not recommended by the manufacturer:
   1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
   2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
   3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
   4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

For patients using Sovaldi with Daklinza, the following must also be met:

A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

- Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing, Accessed February 25, 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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